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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,029	02/23/2004	Franz Enzmann	P63796US1	3780

136 7590 06/16/2006

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WASHINGTON, DC 20004

EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/783,029	<b>Applicant(s)</b> ENZMANN ET AL.	
	<b>Examiner</b> Gollamudi S. Kishore, Ph.D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

### **DETAILED ACTION**

Claims included in the prosecution are 6-21.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

2. Claims 7, 10, 11 and 14-21 1518 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 15 recite, 'formulation further comprises liposome'. It is unclear whether Q10 and other components are encapsulated within the liposomes or the liposomes are empty liposomes.

Claims 10, 11 and 18-19 recite either the administration is to the pulmonary mucosa or gastrointestinal mucosa. It is unclear whether the composition is administered directed over these tissues. Clarification is requested.

It is unclear what 'neutrolipids' is intended to convey in claim 14. Does the term mean 'neutral lipid'?

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,228,891. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in said patent recite a method of treating diseases of the skin and of the mucosa of the mouth, stomach, bowels, vagina and lungs comprising administering to a patient in need thereof; instant claims recite a

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method of rendering skin or mucosa permeable to the Q10 and pulmonary surfactant.

Since a composition is administered to treat a condition of a disease, instant claims are anticipated by the claims in said patent.

***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-10, 13-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461) in view of Pavani (5,273,916), in further combination with Wong (5,451,569) of record: or vice versa, that is, Pavani and Wong in combination Neigut (all are of record).

Neigut teaches a composition for topical application containing Co Q (Q10) for combating aging and skin damage (note the abstract, col. 2, line 5 through col. 3, line 52). What is lacking in Neigut is the teachings of the inclusion of a natural lung surfactant. However, Neigut teaches the phospholipid, lecithin (which is phosphatidylcholine).

Pavani teaches that treating skin with pulmonary surfactant containing phospholipids shows that they interpenetrate with the membranes of the cells present in the derma and encourage the young fibroblasts to proliferate and subsequently produce the precursors of the typical elements of derma (note col. 1, line 48 through col. 2, line 3). Pavani also teaches that a component of pulmonary surfactant fraction, 1,2 dipalmitoyl-L-alpha-phosphatidylethanolamine contributes to the anti-aging of the skin (col. 2, lines 5-15). Pavani's compositions also include liposomes (Examples). What is lacking in Pavani is the inclusion of CoQ. What is also lacking in Pavani is the explicit teaching of the presence of surfactant proteins in combination with the phospholipid fraction of the lung surfactant.

Wong teaches that lung surfactant comprises 90 % phospholipids and 10 % proteins and the major lipid component is dipalmitoylphosphatidylcholine. Wong also teaches that lung surfactant may be extracted and isolated from animal lungs and the surfactant may or may not contain surfactant proteins for use (note column 2, lines 39-48).

To include the lung surfactant in the teachings of Neigut would have been obvious to one of ordinary skill in the art with the expectation of obtaining at least an additive effect in terms of skin anti-aging since Pavani teaches that lung surfactant has the ability to activate the young dermal fibroblasts. The use of the lung surfactant with the proteins would have been obvious to one of ordinary skill in the art because of the equivalency between the lung surfactant with phospholipids (mainly dipalmitoylphosphatidylcholine) and proteins and that without the proteins as taught by

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Wong. Alternately, to include CoQ in Pavani, with a lung surfactant with proteins would have been obvious to one of ordinary skill in the art, with the expectation of obtaining at least similar results since Neigut teaches that coQ produces a anti-aging effect (see also see In re Kerhoven 205 USPQ 1069) and since Wong teaches equivalency between the lung surfactant with phospholipids (mainly dipalmitoylphosphatidylcholine) and proteins and that without the proteins.

6. Claims 6-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461) in view of Pavani (5,273,916), in further combination with Wong (5,451,569) of record: or vice versa, that is, Pavani and Wong in combination Neigut as set forth above, further in view of Mautone (5,306,483).

The teachings of Neigut, Pavani, and Wong have been discussed above. What is lacking in these references is the administration of the composition by the gastrointestinal mucosal route and vaginal routes.

Mautone while disclosing delivery systems for the administration of drugs teaches that phospholipids and pulmonary surfactant proteins A, B, C and D are spreading agents and that the composition can be administered to the skin or mouth, throat (which are parts of gastrointestinal system) and vagina (abstract, col. 2, lines 10-23, col. 10, lines 53-60).

The administration of the liposomal compositions containing Q10 and the pulmonary surfactant composition through mouth or throat or through lungs or vagina would have been obvious to one of ordinary skill in the art with a reasonable expectation

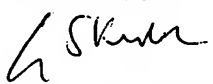
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of success, since Mautone teaches that the compositions containing phospholipids and surfactant proteins could be administered either through lungs, mouth, throat or vagina.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK